

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

<b>IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL 2327</b>  <b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>
<b>THIS DOCUMENT RELATES TO:  WAVE 1 CASES</b>	

**RESPONSE TO PLAINTIFFS' MOTION TO EXCLUDE  
THE OPINIONS AND TESTIMONY OF MARIA ABADI, M.D.**

Ethicon, Inc. and Johnson & Johnson (collectively, “Ethicon”), submit this response (“Response”) to Plaintiffs’ *Memorandum of Law in Support of their Motion to Exclude the Opinions and Testimony of Maria Abadi, M.D.* [Doc. # 1993 (the “Memorandum”)]. The cases to which this Response applies are identified in Ex. A.

**INTRODUCTION**

Dr. Maria A. Abadi, M.D. (“Dr. Abadi”) has been a Board Certified Anatomic Pathologist and Board Certified Cytopathologist for nearly 20 years, having completed two fellowships, the first in Gynecological/Surgical Pathology and the second in Cytopathology. *See* Pls.’ Motion Ex. C, Expert Report of Dr. Abadi (“Abadi Report”) at 1. Dr. Abadi oversees an average of 13,000 surgical pathology and 15,000 cytopathology specimens per year, of which 60 percent are gynecologic cases. *See id.*

Despite these credentials, Plaintiffs argue that Dr. Abadi is unqualified to offer her expert opinion about the human body’s reaction to implanted polypropylene mesh and the related tissue

response. This argument rests upon a false factual assertion and flawed premise— that Dr. Abadi has only reviewed five explanted meshes and, as a result, she is unqualified to reliably testify in this case. That premise lacks foundation for a number of reasons.

- First, Plaintiffs misstate Dr. Abadi’s experience. The record is unrebutted that Dr. Abadi has reviewed 20 to 30 explanted meshes in her clinical practice prior to this litigation—not the mere 5 claimed by the Plaintiffs.
- Second, Dr. Abadi is clearly qualified to render opinions in this case. She is a board certified pathologist who, unlike Dr. Iakovlev, is fellowship trained in gynecological pathology.
- Third, the opinions stated in Dr. Abadi’s report fall within her expertise, are supported by proper methodology, and therefore, are admissible.

For these reasons, the Plaintiffs’ Motion to Exclude the Opinions and Testimony of Maria Abadi, M.D. should be denied.

## **ARGUMENT**

### **I. Legal Standard**

Ethicon incorporates by reference the standard of review for *Daubert* motions articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at \*\*1–3 (S.D.W. Va. July 8, 2014). Under Federal Rule of Evidence 702, an expert may be qualified by “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702.

### **II. Plaintiffs’ Motion Should Be Denied.**

Plaintiffs make three arguments that Dr. Abadi’s testimony should be excluded. *First*, that she is unqualified to offer any opinions regarding Prolene Soft mesh, related tissue response, or its medical sequelae. Memorandum at 3. *Second*, that the basis for her opinions regarding

tissue response are limited to five explant samples she received from Ethicon’s counsel in this litigation, and therefore, her opinions regarding tissue response to Prolene Mesh are unreliable and irrelevant. *Id.* at 5–9. Third, that due to her “limited mesh experience” she cannot critique Dr. Iakovlev’s methodology. *Id.* at 7–9. Each of these arguments is without merit.

**A. Plaintiffs’ argument that Dr. Abadi is unqualified is absurd.**

Plaintiffs argue that Dr. Abadi is unqualified to testify in this litigation because she has only reviewed five mesh samples, handpicked by Ethicon’s counsel. *Id.* at 1, 5. As an initial matter, this is simply untrue. Furthermore, it is a gross distortion of Dr. Abadi’s qualifications.

**1. Dr. Abadi’s qualifications include not only two fellowships, but also include vast clinical experience in gynecologic pathology and numerous scientific publications in peer-reviewed journals.**

Dr. Maria A. Abadi, M.D., is a Board Certified Anatomic Pathologist and Board Certified Cytopathologist. *See* Ex. B, Abadi 3/29/16 Dep. Tr. 21:11–22:15. Dr. Abadi obtained her medical degree from the “Luis Razetti” School of Medicine in Venezuela in 1990, and was the Chief Resident in Anatomic Pathology at the Albert Einstein College of Medicine from 1994 to 1995. Unlike Dr. Iakovlev, who has no specialized training in gynecological pathology, Dr. Abadi completed a fellowship in Gynecological/Surgical Pathology at the Albert Einstein College of Medicine from 1995 to 1996, and completed a second fellowship in Cytopathology at the Memorial Sloan-Kettering Cancer Center from 1996 to 1997. *See* Pls.’ Motion Ex. D, Curriculum Vitae of Dr. Abadi at 1.

Dr. Abadi is currently the Vice Chair of the Pathology Department at Jacobi Medical Center. *See* Pls.’ Motion Ex. C, Abadi Expert Report at 1. She currently serves as Director of Surgical Pathology and Cytopathology laboratories at Jacobi Medical Center, Albert Einstein College of Medicine, Bronx, New York. *See* Ex. B, Abadi 3/29/16 Dep. Tr. 14:19–15:1. In this capacity, she oversees an average of 13,000 surgical pathology and 15,000 cytopathology

specimens per year, of which 60 percent are gynecologic cases. *See* Pls.’ Motion Ex. C, Abadi Expert Report, at 1.

Dr. Abadi also serves as a Professor in the Pathology Department and an Associate Professor in the Department of Obstetrics and Gynecology and Women’s Health at the Albert Einstein College of Medicine. *See* Pls.’ Motion Ex. D, Curriculum Vitae of Dr. Abadi at 3. In addition to her clinical work as a pathologist, she is also a published research scientist, and has published 29 peer-reviewed scientific articles. *See id.* at VIII–XI.

**2. Based on her extensive education, experience, knowledge, training, and skill Dr. Abadi is qualified to provide all the opinions in her report.**

Plaintiff’s argument is based upon a faulty premise—that a pathologist must be a “mesh pathologist” to render an opinion regarding the body’s reaction to mesh. This is simply false. Pathologists review tissue slides every day to determine the body’s reaction to foreign bodies. The process by which this assessment is made is the same regardless of the composition of that particular foreign body. During the course of this MDL, this Court has repeatedly found pathologists to be qualified to provide testimony regarding their findings related to pathology. *See, e.g., Frankum v. Bos. Sci. Corp.*, No. 2:12-CV-00904, 2015 WL 1976952, at \*24 (S.D.W. Va. May 1, 2015) (anatomical and clinical pathologist qualified to testify about pathology of mesh material despite lack of training in polymer science or testing of mesh products). Similarly, in the *Bellew* case, plaintiffs raised the identical challenges to Ethicon’s expert, Dr. Stanley Robboy. *Op.* at 37–41, *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473 (S.D.W. Va. Nov. 20, 2014) [Doc 265]. In that case, plaintiffs also claimed that a nationally prominent, fellowship trained gynecological pathologist was unqualified because he “didn’t have pelvic mesh experience” and the experience he did have was derived through litigation. *Id.* at 37. This Court rejected the

challenge to Dr. Robboy, finding that his testimony was permissible because he had done the following things:

- His opinions were based upon his professional experience gained through his clinical practice.
- He reviewed the plaintiffs' medical records.
- He reviewed the explant samples both grossly and microscopically.

This is exactly what Dr. Abadi did in this case. She formulated her pathology opinions using the standard methods employed by pathologists. Specifically, she examined pathological slides and identified the presence or absence of certain features, which is the precise methodology pathologists follow in their practice. *See Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 532 (S.D.W. Va. 2014) (explaining that a pathologist used "reliable pathology methods" where "he reviewed slides, considered the possible causes[], and came to a diagnostic conclusion").

**B. Plaintiffs' argument that Dr. Abadi's opinions are unreliable and irrelevant because she has only reviewed five mesh samples, handpicked by Ethicon's counsel, is factually false.**

The crux of Plaintiffs' "qualifications" argument is set forth in the argument heading on the first page of their Memorandum: "Dr. Abadi's experience in reviewing Prolene Mesh is limited solely to this litigation and solely to the few samples Ethicon counsel provided to her." Plaintiffs then argue that Dr. Abadi has only reviewed five mesh explants. Memorandum at 5.

Plaintiffs' assertion that Dr. Abadi bases her opinion "entirely" on reviewing five explanted meshes given to her by defense counsel is simply false. Dr. Abadi reviewed and relied upon a number of sources and publications in preparing her report, including the 25 items listed in the bibliography of her report. *See* Pls.' Motion Ex. C, Abadi Expert Report at 13–15; *see also* Ex. B, Abadi 3/29/16 Dep. Tr. 168:23–170:5. Additionally, the assertion that the number of

meshes she has seen is five is incorrect as well. Dr. Abadi's actual testimony was that she has seen **two to three polypropylene pelvic meshes per year, for the last ten years**, in her clinical practice. Ex. B, Abadi 3/29/16 Dep. Tr. 170–71. Thus, the actual number of pelvic meshes Dr. Abadi reviewed in her clinical practice prior to becoming involved in this litigation was 20 to 30, not five.

In her deposition, Dr. Abadi explained that the human body's inflammatory response to polypropylene is the same regardless of where it is implanted. *See id.* at 170:24–171:4. Dr. Abadi explained that, in addition to the 20 to 30 pelvic meshes she has reviewed, she has also reviewed polypropylene hernia meshes in her clinical practice. *Id.* at 171–72. Moreover, Dr. Abadi has reviewed more than a 1,000 pathology samples containing sutures, many of which were made of polypropylene and demonstrate the same inflammatory response as pelvic mesh made from polypropylene. *Id.* at 171:5–15.

### **III. Dr. Abadi is Qualified to Testify Regarding All of the Opinions Contained in her Expert Report.**

Plaintiff's final claim is that Dr. Abadi's opinion pointing out the flaws in Dr. Iakovlev's methodology, Pls.' Motion Ex. C, Abadi Expert Report at 9–12, must be excluded. Memorandum at 8. Plaintiff makes a hybrid argument that: (a) that such arguments are unreliable general causation arguments framed as rebuttal; and (b) that "these opinions are again based on her review of five explanted mesh samples provided her by Defendant, and a review of Plaintiff's expert report." *Id.*

Dr. Abadi will inform the jury that it is impossible for a pathologist to conclude that a particular finding caused clinical complications in a patient based solely on a review of pathologic slides. Dr. Iakovlev's assertions that he can make such causal conclusions have no basis in the field of pathology. *See, e.g.,* Ex. C, Susan Lester, Manual of Surgical Pathology 3

(2010) (“It has been shown that pathologists cannot accurately predict clinical information from the glass slides alone.”). In short, Dr. Abadi’s testimony will demonstrate that Dr. Iakovlev’s analysis is methodologically flawed and inaccurate.

In her Report, Dr. Abadi explains at length the basis for her opinion in regard to each area in which she attacks Dr. Iakovlev’s methodology: (1) pain and nerve damage, Pls.’ Motion Ex. C, Abadi Expert Report at 9–10; (2) mesh stiffening, contraction, and shrinkage, *id.* at 10; (3) deformation and mesh migration, *id.* at 9–10; (4) polypropylene degradation, *id.* at 11–12; (5) degenerative calcifications, *id.* at 12; and (6) mucosal erosion and tissue edema, *id.* at 12. Dr. Abadi also points out numerous errors in the photographs Dr. Iakovlev uses to support his faulty methodology on these topics. *See* Pls.’ Motion Ex. C, Abadi Expert Report, at App’x B (critiquing photo sets 1(a) through 20(b)).

In regard to Dr. Iakovlev’s opinions that pelvic mesh causes pain and nerve damage, Dr. Abadi explains that the presence of inflammatory cells or scar tissue does not correlate with pain. *See* Pls.’ Motion Ex. C, Expert Report at 9; *see also* Hill et al., *Histopathology of excised midurethral sling mesh*, 26 Int’l Urogynecology J. 591–595 (2015) (referenced in Dr. Abadi’s bibliography at 14, attached as Ex. D). She further explains why the histological examination of explanted mesh material does not correlate with the pain that is (or is not) experienced by the patient. *See* Pls.’ Motion Ex. C, Abadi Expert Report at 9. She also points out the flaws in Dr. Iakovlev’s use of pathological stains to identify nerves, particularly his extrapolation of findings from H&E and S-100 stains, and explains that these stains cannot identify nerve receptors and, therefore, do not permit a pathologist to draw the conclusions asserted by Dr. Iakovlev. *Id.* at 9–10. Furthermore, she explains that Dr. Iakovlev draws conclusions about nerves in histological

slides based upon their appearance post-processing, which, of course, is markedly different than their appearance *in vivo*. *Id.* at 10; *see also id.* at App'x B, critique of fig. sets 3 & 4.

The bases for Dr. Abadi's opinions in the remaining five areas in which she critiques Dr. Iakovlev's methodology are also spelled out in her report at pages 10 through 12 and Appendix B. In regard to mesh "stiffening, contraction and shrinkage" she explains that mesh contraction is caused by the normal processes of wound healing and not an alleged defect in the mesh as claimed by Dr. Iakovlev. Pls.' Motion Ex. C, Abadi Expert Report at 10.

In regard to alleged "Deformation and Mesh Migration," Dr. Abadi points out the difference between the histological presentation of the mesh post-explantation and explains why it cannot be used to draw conclusions about the qualities of the mesh *in vivo*. Obviously, once the mesh has been excised by cutting and/or cauterization by the explanting surgeon and then treated with chemicals to preserve the sample, the mesh is no longer in the same condition as it was *in vivo*. Yet, Dr. Iakovlev presents pictures of the explanted mesh and uses these pictures to draw conclusions about its *in vivo* characteristics. *See id.* at 10–11; *see also id.* at Appendix B, critique of fig. sets 10 & 11. Dr. Abadi explains that in most of Dr. Iakovlev's slides the mesh isn't even present, having been removed by the cutting blade during the microtoming process. Pls.' Motion Ex. C, Adadi Expert Report at 11. Because the mesh is not even present, Dr. Iakovlev uses Photoshop to highlight his pictures and pretend that they display mesh when they do not.

Dr. Iakovlev's contention that he can look at a pathology slide and infer that mesh curled or deformed in the human body prior to explantation is baseless. As an initial matter, Dr. Iakovlev fails to follow the standard methodology used by pathologists for determining how a specimen is oriented in the human body. Additionally, as Dr. Abadi explained in her deposition testimony, there is a process by which surgeons and pathologists can position tissue as it was



oriented *in vivo*. This involves tagging the tissue to show its orientation and then the pathologist pins the tissue to a board to ensure that its orientation remains the same during tissue processing. To ascertain how a specimen was oriented *in vivo*, a pathologist must (i) identify anatomical landmarks and (ii) consult markers provided by the explanting surgeon. Ex. E, William Westra, et al., *Surgical Pathology Dissection* at 4 (2003); Ex. C, Lester at 7. Specifically, the surgeon must use sutures, tags, or a diagram to designate the orientation (*i.e.*, anterior, posterior, medial, lateral, superior, and inferior positioning) of the specimen. *See* Ex. E, Westra at 4; Ex. C, Lester at 7. The failure to adhere to this methodology at the time of explantation limits, if not eliminates, the pathologist's ability to determine the *in vivo* orientation of the specimen and renders conclusions as to its *in vivo* appearance speculative. *See* Ex. E, Westra at 4; Ex. C, Lester at 7.

Dr. Iakovlev did not follow this methodology in developing his folding opinions. Rather, he simply concludes that a specimen that has a folded appearance during his examination was also folded *in vivo*. But as Dr. Abadi explained, "if [a mesh] comes [out] folded, it has nothing to do with the way it was positioned *in vivo*" because the explanting surgeon subjects the explant to a variety of forces during the removal. *See* Ex. B, Abadi 3/31/16 Dep. Tr. 99:19–101:9 (explaining that without information from the surgeon, orientation of a specimen is "all speculation"). As Dr. Abadi will point out at trial, Dr. Iakovlev fails to follow this standard methodology. Pls.' Motion Ex. C, Abadi Expert Report at 10–11.

In addition, Dr. Abadi will explain that the methodology employed by Dr. Iakovlev to detect the purported degradation of Prolene lacks any foundation in the field of pathology. Specifically, Dr. Abadi will testify that, although Dr. Iakovlev claims he can identify degraded Prolene using certain histological stains and polarized light, these tools simply do not work in the

manner Dr. Iakovlev claims as a matter of fundamental pathology. *Id.* at 11. Dr. Abadi will explain that pathologists routinely use chemical stains that identify acidic nucleic acids or basic proteins by forming chemical bonds with those substances, as well as immunohistochemical stains that distinguish between cells and identify cell components. *Id.*; *see also id.* at App'x B, critique of fig. sets 13–19. For example, Dr. Abadi will explain that the layer of purported degraded polypropylene accepts Periodic Acid Schiff Stain. *Id.* at 11; *see also id.* at App'x B, critique of fig. sets 13–19. This means that the outer layer of the purportedly degraded Prolene contains protein and is not degraded Prolene at all—as claimed by Dr. Iakovlev. Dr. Abadi also explains that there is no basis in science—much less in the field of pathology—for Dr. Iakovlev's assertion that a pathologist can use these tools to identify degradation in polymers. *Id.*

Dr. Abadi uses the tools of the pathologist, the review of tissue samples using stains, and a light microscope to opine that even if Dr. Iakovlev is correct that there is a 1 to 5 micron-thick layer of degraded polypropylene shown in his slides, that layer has no clinical significance for the patient. *Id.* at 11. As Dr. Abadi explains, there is no difference between the tissue reaction in areas where the alleged degradation layer is present and in areas where the alleged degradation layer is not present. *Id.*

The final two areas where Plaintiffs challenge Dr. Abadi's critique of Dr. Iakovlev—degenerative calcifications and mucosal erosions—are similarly flawed. In fact, it's almost laughable that Plaintiffs argue that a fellowship trained gynecological pathologist like Dr. Abadi is not qualified to testify about these anatomical features in vaginal tissue while arguing that Dr. Iakovlev—who has no specialized training in degenerative calcifications and mucosal erosions—is qualified to opine about these anatomical features. In any event, Dr. Abadi's report explains

the basis for her testimony and methodology critiquing Dr. Iakovlev on these topics. *Id.* at 12; *id.* at App'x B, critique of fig. set 20-a-20b.

All of these opinions—from Dr. Abadi's review of Dr. Iakovlev's pathology photographs to her testimony regarding the generally accepted methods used by pathologists—are clearly within the scope of Dr. Abadi's expertise derived from her extensive education, training, and experience. Plaintiffs' arguments to the contrary are without merit, and should be rejected by this Court. *See Fuji Elec. Corp. of Am. v. Fireman's Fund Ins.*, No. 9:05CV27, 2005 WL 5960354, at \*2 (E.D. Tex. Nov. 21, 2005) (explaining that "examin[ation] and critici[sm] of the work of another expert" "is one of the traditional roles of an expert); *see also* Fed. R. Civ. P. 26(a)(2)(D) (providing for the disclosure of rebuttal expert witness opinions "intended solely to contradict or rebut evidence on the same subject matter identified by another party").

### **CONCLUSION**

For the foregoing reasons, Ethicon requests that the Court deny Plaintiffs' motion to exclude the expert testimony of Dr. Abadi and grant such other and further relief as the Court deems proper under the circumstances.

Respectfully submitted,

/s/ David B. Thomas

David B. Thomas (W.Va. Bar #3731)

Thomas Combs & Spann PLLC

300 Summers Street

Suite 1380 (25301)

P.O. Box 3824

Charleston, WV 25338

(304) 414-1800

[dthomas@tcspllc.com](mailto:dthomas@tcspllc.com)

/s/ Christy D. Jones

Christy D. Jones  
Butler Snow LLP  
1020 Highland Colony Parkway  
Suite 1400 (39157)  
P.O. Box 6010  
Ridgeland, MS 39158-6010  
(601) 985-4523  
[christy.jones@butlersnow.com](mailto:christy.jones@butlersnow.com)

COUNSEL FOR DEFENDANTS ETHICON, INC.  
AND JOHNSON & JOHNSON

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**CERTIFICATE OF SERVICE**

I hereby certify that on May 9, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

/s/ David B. Thomas

David B. Thomas (W. Va. Bar No. 3731)  
Thomas Combs & Spann, PLLC  
300 Summers Street, Suite 1380  
P.O. Box 3824  
Charleston, WV 25338-3824  
(304) 414-1800

COUNSEL FOR DEFENDANTS ETHICON, INC.  
AND JOHNSON & JOHNSON